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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/577,468	05/24/2000	Vivien W. Wong	REG 142-C	5396

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EXAMINER
HAYES, ROBERT CLINTON

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 03/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/577,468	Applicant(s) Wong et al
	Examiner Robert C. Hayes, Ph.D.	Art Unit 1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 6, 2003* .

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-5 and 7-19* is/are pending in the application.

4a) Of the above, claim(s) *5, 13-17, and 19* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-4, 7-12, and 18* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-5 and 7-19* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Response to Amendment

1. The amendment filed 1/06/03 has been entered.

2. The rejections of claims 6 & 8-12 under 35 U.S.C. 101, or under 35 U.S.C. 112, first paragraph, because the claimed invention is not supported by either a credible asserted utility or a well established utility, are withdrawn due to the cancellation of claim 6.

3. The rejection of claims 1-2 & 4 under 35 U.S.C. 112, first paragraph, for lack of enablement is withdrawn due to the amendment of the claims.

4. The rejections of claims 1-4, 6-12, 18 & 20-22 under 35 U.S.C. 112, second paragraph, are withdrawn due to either the cancellation or amendment of the claims.

5. The rejection of claim 1-4, 7, 9-12 & 18 under 35 U.S.C. 102(b) as being anticipated Cilberto et al (WO 98/22128), is withdrawn due to either the cancellation or amendment of the claims.

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Applicants' arguments filed 1/06/03 have been considered but are not found persuasive.

8. This application contains claims 5, 13-17 & 19 drawn to inventions nonelected with traverse in Paper No. 9. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

9. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). It is noted that none of the priority applications for Application No. 09/031,693 are listed within the first sentence of the specification.

10. The reference of publications in the response fails to comply with 37 CFR 1.98(a)(1) for filing an IDS, which requires a list of all patents, publications, or other information submitted for consideration by the Office. It has been placed in the application file, but the information referred to therein has not been considered beyond the brief statements made in the response.

11. Claims 1-4, 7-12 & 18 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 7 & 11 of copending Application No. 09/454380, for the reasons made of record in Paper NO: 10 (mailed 7/30/02).

Although the conflicting claims are not identical, they are not patentably distinct from each other because each application recites overlapping methods of treating diabetes in humans through administering AX-15.

In contrast to Applicants' assertions on page 3 of the response, claims which generically recite "administration" encompass "nasal or respiratory" modes of administration, by definition; thereby, encompassing the claims of the instant application.

12. Claims 3, 7-12 & 18 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of reducing body weight/fat and food intake in obese mammals while attenuating obesity associated hyperinsulinemia/ reducing diet-restricted plasma insulin levels following administration of the modified human ciliary neurotrophic factor of SEQ ID NO:1 further consisting of C17A, Q63R, ΔC15 (i.e., Ax-15 of SEQ ID NO: 16 or 17), does not reasonably provide enablement for the treatment of diabetes in general. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims, for the reasons made of record in Paper NO: 10 (mailed 7/30/02), and as follows.

In contrast to Applicants' assertions, referral to an application (i.e., 09/454,380) that is no longer claimed as a priority document, or not incorporated by reference, cannot reasonably enable a different application. In other words, the court in *In re* Hogan and Banks, 194 USPQ 527 (1977) makes clear that enablement must be established *in the specification at the time of filing*

and is to be *commensurate in scope* with the stated claims. Moreover, because the claims are not limited to "producing a significant reduction in insulin resistance, a corresponding increase in insulin sensitivity, and [or] improved glucose disposal", Applicants' arguments are not persuasive, for the reasons previously made of record; especially when drugs such as "Troglitazone and Metformin" do not reasonably interact with the CNTF receptor, and therefore, also do address what metes and bounds "treating gestational and adult onset diabetes" or "treating an [undefined] disorder responsive to CNTF" entail without requiring undue experimentation to discover such after-the-fact, as currently claimed. Again, note that no guidance is provided within the specification on how to specifically "treat" these disorders with their different etiologies, if known, and/or what times and under what conditions or under what physiological parameters "treatment" is to be accomplished, except as it relates to murine models for diet-induced obesity using specific strains of obese mice (i.e., *ob/ob* and AKR/J; pages 26-30 of the specification), as previously made of record. Thus, these claims remain not enabled for the reasons made of record.

It is suggested, for example, that claim 3 be rewritten to "...wherein excess weight [method is for treatment of] is due to diet-induced obesity" should more clearly define the invention and obviate this rejection of claim 3.

13. Claims 8-11 & 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8-11 & 13 are dependent on either cancelled claim 6 and/or nonelected claim 5.

14. Claims 1-4, 6-12, 18 & 20-22 stand rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter, for the reasons made of record in Paper NO: 10 (mailed 7/30/02).

In contrast to Applicants' assertions on page 5 of the response, the three inventors of the instant application still are entirely different from the three inventors in Application No.09/454,380, who also claim treating obesity and diabetes with Ax-15, in which the same assignee submitted both applications; thereby, still placing in doubt who actually invented the instant invention. In other words, having the instant application no longer claim priority to Application No.09/454,380 does not address who actually invented the instant invention.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert C. Hayes, Ph.D.
March 26, 2003

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600